FEB - 9 2005

K093188

EXHIBIT 2

510(k) Summary

Q3 INNOVATIONS, LLC
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Telephone: 651-762-5728
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November 2, 2004

Contact: Brian Eddy, CEO/CFO

1. **Identification of the Device:**

   Proprietary-Trade Name: Alcohawk Precision™ Digital Alcohol Detector

   Classification Name: Device, breath trapping, alcohol, DJZ

   Common/Usual Name: Breath-alcohol test system

2. **Equivalent legally marketed devices** AlcoMate CA2000™ Digital Alcohol Detector manufactured by Han International, K041334

3. **Indications for Use (intended use)** : The device is intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

4. **Description of the Device**: The Alcohawk Precision™ is designed to measure deep lung air to test for the presence of alcohol in the blood. The relationship between alcohol in the blood and alcohol in the deep lung breath is well established by Henry's law in ratio of 2100:1 The Alcohawk Precision™ is a D.O.T. approved alcohol screening device and uses a blow time of 5 seconds to capture an accurate deep lung sample. The Alcohawk Precision™ contains a semiconductor oxide sensor designed to test for the presence of alcohol. Gas sensitive semiconductor material is formed on an alumina substrate on which the gold electrodes are printed. A thick film heater of ruthenium oxide is printed on the reverse of the substrate and placed in the plastic housing. The tin dioxide (SnO2) metal oxide semiconductor material is heated to a specific temperature. The resistance of sensing material changes rapidly according to gas concentration changes, thereby enabling the reading of alcohol concentration by resistance measurement.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, DOT, and user testing indicates that the new device is as safe and effective as the predicate device. A clinical trial was performed to establish that the user could read and understand the instructions provided, and properly use the device.

6. Substantial Equivalence Chart

Feature	AlcoMate CA2000 K041334	Alcohawk Precision™
INDICATION For USE	The device is intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	SAME
MODE	Breath Alcohol Concentration	SAME
PRACTITIONER USE	Over the Counter	SAME
DISPLAY	3 Digit LED	4 Digit LED
POWER SOURCE	9 Volt Alkaline Battery	SAME,
BATTERY LIFE	300 Tests	100-300 tests
Measurement Range	.00-.40%	SAME
Accuracy	+/-0.01%	SAME (+/- .009%)
TYPE OF SENSOR	Semiconductor-Oxide Sensor	SAME
ANATOMICAL SITE	Mouth	SAME
Mouthpiece	Replaceable	SAME
Warm Up Time	20 Seconds	15-60 Seconds
Blowing Time	5 Seconds	SAME
DOT Approval	YES	YES
Construction	Plastic case with internal circuit board	SAME
SIZE	5" x 3 ½"	4.25" x 2.75"
WEIGHT	200 grams	130 grams

7. Conclusion

After analyzing bench tests, a risk analysis, electrical safety, EMC, DOT testing and user testing data, it is the conclusion of Q3 INNOVATIONS, LLC that the Alcohawk Precision™ is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device. The clinical trial performed showed that the over the counter purchaser of this device could read and understand the instructions, could properly use the device, and obtain results that were comparable to those provided by a professional unit administered by a trained observer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Q3 Innovations, LLC
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
Deerfield, IL 60015

Re: k043188
Trade/Device Name: AlcoHawk™ Precision
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I
Product Code: DJZ
Dated: November 5, 2004
Received: November 26, 2004

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043188

Device Name: AlcoHawk™ Precision

Indications For Use: Intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043188